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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,824	10/23/2003	Robert Burgermeister	CRD1061CIP2	6326

27777 7590 06/16/2006

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,824	BURGERMEISTER, ROBERT	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 03/27/2006, amended claims 1, 16, and 26 and cancelled claim 39 is/are acknowledged. The current rejections of the claims 1-38 are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 01/26/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 16-18, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran et al (US 5,908,405). For claims 1, 16, and 26, Imran et al discloses a steerable balloon catheter 11, 71,151, comprising:

- (a) an inner flexible tube 24,86,171 and an outer flexible tube 17,53,73,152 defining an inner lumen 16,76,156 between said inner and outer tubes;
- (b) an inflatable balloon 96 mounted on said outer tube and communicating with said inner lumen;

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- (c) a flexible helical coil 101,181 fixedly attached about the distal portion of said flexible tubing via adhesive 102,182;
 - (d) a tapered elongated deflection member 78 slidably disposed within said tubing and helical coil wherein the distal portion is flattened forming a deflection ribbon extending in a plane and having a proximal circular cross section (column 7 lines 3-9);
 - (e) a retaining ribbon 111 disposed about the distal region of the flexible tubing and oriented in a plane parallel to that of the deflection ribbon; and
 - (f) an attachment member 103 engaging the distal end of the helical coil, the deflection member and the retaining ribbon wherein longitudinal movement (push or pull) of the deflection member causes deflection of the distal tip in two opposing directions (column 11 lines 26-30).
5. For claims 2, 17, and 27, Imran et al discloses said retaining and deflection ribbons having a normally biased arcuate configuration thereby curving the distal end of said guiding wire for balloon catheter placement (column 12 lines 7-13).
6. For claims 3 and 4, Imran et al discloses a steerable balloon catheter comprising a tapered elongated deflection member 78 extending from the proximal portion to approximately the distal portion of said inner tubing and having a circular cross section (column 7 lines 3-9) and further comprising a retaining ribbon 111 extending from the distal region of the flexible tubing to approximately the distal end of said flexible helical coil.

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7. For claims 5 and 18, Imran et al discloses a steerable balloon catheter wherein said attachment member 103 takes a rounded ball shape (column 7 lines 28-31).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-10, 19-22, 28-32, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al in view of Schaer et al (US 5,882,333). For claim 6, Imran et al discloses the claimed steerable balloon catheter except for the attachment member shaped as a rounded bead formed with a suitable adhesive, e.g. epoxy. Schaer et al teaches a steerable catheter 10 using suitable adhesive or epoxy for forming the attachment member 35 (column 5 lines 43-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of utilizing a biocompatible adhesive rather than a weld to fixably secure distal elements of the guidewire.

10. For claim 28, Imran et al discloses the claimed steerable balloon catheter except for the retaining ribbon having a circular cross section wherein the distal portion is flattened. Schaer et al teaches a steerable catheter comprising a retaining ribbon 31,64 with a flattened distal portion as best seen in Figures 2 and 5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature

11. For claims 7, 19, and 29, Imran et al discloses the claimed steerable balloon catheter except for the deflection ribbon engaging the rounded bead attachment member at a location offset the center of the circular surface created by the engagement of the coil with the attachment member. Schaer et al teaches the engagement of a deflection member 32,65 at a location offset the center of said attachment member as best seen in Figures 2, 5, and 21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

12. For claims 8, 20, and 30, Imran et al discloses the distal end of said retaining ribbon engaging said rounded bead attachment member at a location offset the center of said attachment member as best seen in Figure 6.

13. For claims 9, 21, and 31, Imran et al discloses the claimed steerable balloon catheter, including the distal end of said retaining ribbon engaging said rounded bead attachment member at a location offset the center of said attachment member, except for the deflection ribbon engaging the rounded bead attachment member at a location offset the center of the circular surface created by the engagement of the coil with the attachment member and in an opposite direction than the retaining ribbon. Schaer et al

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teaches, using incorporated reference Nitzsche (5190050), the engagement of retaining ribbon 48 and deflection ribbon 52 to the attachment member in opposite directions offset from the center of said attachment member as best seen in Figures 5 and 6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

14. For claims 10, 22, and 32, Imran et al discloses the claimed steerable balloon catheter, including the engagement of a deflection member and retaining ribbon within said attachment member, except for the joining of the retaining and deflection ribbons within the rounded bead attachment member. Schaer et al teaches the joining of the deflection and retaining ribbons (column 5 lines 44-49) as best seen in Figure 9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature and to shape the distal end of the guidewire prior to insertion.

15. For claims 36-39, Imran et al discloses the claimed steerable balloon catheter except for the control handle coupled to the flexible tubing with a release mechanism and also coupled to the deflection member which extends the entire length of and proximally beyond the handle including movable knob coupled to the deflection member for longitudinal positioning. Schaer et al teaches a control handle 14 coupled to the

flexible tubing 11 including a release mechanism for said coupling and also coupling to the deflection member 32 extending the length of and beyond the handle proximally wherein said control handle comprises a movable knob 48 coupled to the deflection member for longitudinal positioning. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the proximal portion of the balloon catheter for ease of and enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

16. Claims 11-15, 23-25, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al in view of Schaer et al and in further view of Bagaoisan et al (US 6,355,016). For claims 11, 12, 23, 24, and 33, Imran et al and Schaer et al disclose the claimed steerable balloon catheter except for the deflection and retaining ribbons formed as a single unitary element forming a generally U-shaped configuration with a predetermined spacing therein causing the two opposing sides to be parallel. Bagaoisan et al teaches a deflection/retention member 120 formed as a single unitary element with a generally U-shaped configuration, a predetermined spacing therein causing the two opposing sides to be parallel as best shown in Figure 4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al and Schaer et al, with Bagaoisan et al for the purpose of configuring the distal portion of the balloon catheter for enhanced control over distal bi-directional deflection means for navigating tortuous

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vasculature, to shape the distal end of the guidewire prior to insertion, and to reduce the amount of material needed to form said apparatus.

17. For claims 13-15 and 34-35, Imran et al and Schaer et al disclose the claimed steerable balloon catheter except for the flattening of intermediate and distal portions of the deflection member to create both deflection and retaining ribbons wherein the thickness of the flattened most distal region, the retaining ribbon equal to about 0.0015 inches, is less than the thickness of the flattened intermediate region, the deflection ribbon equal to about 0.002 inches. Bagaoisan et al teaches a deflection/retention member 120 distally tapered wherein the thickness of the intermediate portion, the deflection ribbon, is greater than that of the most distal portion, the retaining ribbon, and flattened to a thickness of approximately 0.002 inches inherently capable of increased flattening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al and Schaer et al, with Bagaoisan et al for the purpose of configuring the distal portion of the balloon catheter for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature, to shape the distal end of the guidewire prior to insertion, and to reduce the amount of material needed to form said apparatus.

18. For claim 25, Imran et al discloses a steerable balloon catheter wherein said attachment member 103 takes a rounded ball shape (column 7 lines 28-31).

Response to Arguments

19. Applicant's arguments filed 03/27/2006 have been fully considered but they are not persuasive.

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20. Applicant argues: (a) element 86 of Imran et al is not an inner flexible tube, but is, in sharp contrast, a solid core wire and (b) flexible helical coil of Imran et al is not attached to the distal portion of the flexible tube.

21. The examiner notes Imran et al discloses the invention as broadly as structurally claimed, specifically: (a) Imran discloses (column 7 lines 8-10) element 86 is an insulating coating of core wire 78, which structurally defines an inner flexible tube and (b) Imran discloses bonding the coil to the coated core wire (column 7 lines 31-34).

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

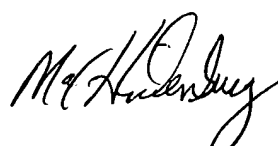
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH



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